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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,626	08/05/2003	Gregory M. Glenn	056707-5009-01	6381
9629	7590	07/08/2005	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER

1644

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/633,626

Applicant(s)

GLENN ET AL.

Examiner

Yunsoo Kim

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-7, 11, 13, 14, 16, 19, 31, 38 and 46-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-7, 11, 13, 14, 16, 19, 31, 38 and 46-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/23/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Claims 2-7, 11, 13-14, 16, 19, 31, 38 and 46-60 are pending.
2. Applicant's species election with traverse in the reply filed on 6/1/05 is acknowledged. Upon further consideration, the species election has withdrawn.

Claims 2-7, 11, 13-14, 16, 19, 31, 38 and 46-60 are under consideration in the instant application.

3. Applicants' IDS filed on 2/23/04 is acknowledged. However, the foreign documents and non-patent literatures have not been considered because the copies of references were not available to examiner.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 2-7, 11, 13-14, 16, 19 and 31 are rejected under 35 U.S.C.112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification as filed does not provide a written description or set forth the metes and bounds of the phrases "the formulation is applied in an amount and for a length of time effective to induce an immune response specific for the at least one antigen" and "genetically altered toxin". The specification does not provide direction for the above-mentioned phrases as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. Applicant is required to cancel the new matter in the response to this Office Action.

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Alternatively, Applicant is invited to provide clearly point out the written support for the instant limitations.

6. Claims 2-7, 11, 13-14, 16, 19, 31, 38 and 46-60 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not reasonably provide enablement for a method of inducing an immune response comprising applying a formulation to intact “dry” skin of subject wherein the formulation is comprised of at least one antigen and at least one adjuvant wherein the formulation is applied in “dry” form.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

There is insufficient guidance in the specification as filed as to how the skilled artisan would use the dry formulation comprising an antigen and adjuvant to intact dry skin to induce immune response to achieve the intended use of the claimed invention without undue experimentation.

As disclosed in the specification of instant application, p. 32-52, examples 1-7, the working examples and data which shown induced immune responses are either pretreated with aqueous media or applying antigen/adjuvant formulation in aqueous form. As seen on Table 3, no immune response was induced without pretreatment of skin and powder form of antigen.

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Furthermore, Applicant has no working examples demonstrating the application of the dry formulation on dry skin induce immune responses.

Thus, Applicant has not provided any guidance to enable one skill in the art to use claimed invention in manner reasonably correlated with the scope of enablement. In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 2-5, 7, 11, 13, 14, 16, 19, 31, 38, 46-48, 51-54, 56, 58-60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 5,910,306 (IDS ref. VL).

The '306 patent teaches a method of inducing immune response (claims 1-8) comprising formulation comprising an antigen and adjuvant (i.e. liposome encapsulating antigen and adjuvant, col. 4, lines 58-60).

As the reference teaches the liposome containing antigen and adjuvant can be lyophilized (i.e. dry form col. 4, lines 28-35, col. 12, example 2) and application of said formulation to dry skin of subject (i.e. intact, col. 2, lines 64-65), and effective length of time to induce immune response is inherent property as the intended use of the claimed invention is achieved, the reference teachings meet the limitation of claim 2.

Claim 31 is included because cleaning the surface with alcohol before application of medication is well known procedure.

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The '306 patent further teaches the use of occlusive dressing covering the surface area larger than draining lymph node field (col. 8, lines 65-68, col. 9, lines 26-31), includes adjuvants such as cytokine and chemokines (col. 6-7 overlapping paragraph), antigens including lipid, bacteria (anthrax), viruses (influenza, rabies) (col. 6, lines 15-60), formulation with or without adjuvants (col 4, lines 51-60) and antigen specific responses (claims 1-8).

The '306 patent also teaches a single molecule acting both antigen and adjuvant (i.e. cholera toxin col. 11, lines 25-30) and the transdermal delivery method provides delivery of antigens to the immune system specialized immune cells underlying the skin (col. 4, lines 51-60).

Thus, reference teachings anticipate the claimed invention.

9. Claims 2-7, 11, 13, 14, 16, 19, 31, 38 and 46-60 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 5,980, 898 (IDS ref. VR).

The '898 patent teaches a transcutaneous immunization with a patch comprising an antigen and adjuvant (claims 1-9).

As the reference teaches the liposome containing antigen and adjuvant can be lyophilized (i.e. dry form, col. 11, lines 60-65) and application of said formulation to dry skin of subject (i.e. intact, col. 3, lines 42-43, col. 12, 44-46, option to "hydrate but not required" reads on dry), and effective length of time to induce immune response is inherent property as the intended use of the claimed invention is achieved, the reference teachings meet the limitations of claim 2.

The '898 patent further teaches the use of occlusive dressing covering the surface area larger than draining lymph node field (col. 3, lines 30-33, claims 2-5), includes adjuvants such as cytokine, chemokines (col. 9, lines 40-53), ADP-ribosylating exotoxin as an adjuvant (col. 9, lines 62-68).

The '898 patent also teaches antigens including lipid, bacteria (anthrax, col. 9, lines 6), viruses (influenza, rabies, col. 9, lines 20-21), attenuated live virus (col. 11, lines 41-46), multivalent antigen (col. 3, line 35), antigen specific responses (claims 1-6) and a single molecule acting both antigen and adjuvant (i.e. cholera toxin col. 10, lines 27-32).

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Thus, reference teachings anticipate the claimed invention.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2, 6, 49, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,910,306 (IDS ref. VL) in view of U.S. Pat. No. 5,988,898 (IDS ref. VR)

The teachings of '306 patent have been discussed, supra.

The '306 patent does not teach a use of ADP-ribosylating exotoxin and heat-labile enterotoxin

However, the '898 patent teaches use of ADP-ribosylating exotoxin and heat-labile enterotoxin with an antigen in transcutaneous immunization because ADP-ribosylating exotoxin target specialized antigen presenting cells, Langerhans cells, underlying the skin (cols. 5-6).

Therefore, one of the ordinary skill in the art would have been motivated to combine the ADP-ribosylating exotoxin or heat-labile enterotoxin as taught by the '898 patent to the method to induce immune response with antigen-adjuvant formulation taught by the '306 patent to increase specificity of the immune response.

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From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 2 and 38 are provisionally rejected under the judicially created doctrine of double patenting over pending claim 1 of copending Application No. 11/109,948 and claim 1 of copending Application No. 10/435,676. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising and antigen and an adjuvant to skin.

14. No claims are allowable.




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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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